

R E M A R K S

Claims 1-13 and 20 are pending. Claims 14-19 and 21 have been cancelled and claims 1-3, 6, 10-13 and 20 have been amended.

Applicant submits that no new matter has been added by way of the present submission. For instance, the specification has been amended to recite the full name for GM1a as Galb1-3GalNAcb1-4(NeuAca2-3)Galb1-4G1cb1-1'Cer as supported by Table 1, page 10 of the present specification. Claim 1 has been amended to indicate that the nucleotide sequence of (C) and (D) encodes a polypeptide that has the activity of hydrolyzing any one of substances selected from the group consisting of (i) N-Lauroylsphingosine, (ii) N-Palmitoylsphingosine, (iii) N-Stearoylsphingosine, (iv) N-Palmitoylsphinganine, (v) N-Stearoylsphinganine, and (vi) 12-((N-(7-nitrobenz-2-oxa-1,3-diazol-4-yl)amino)dodecanoyl)sphingosine. Table 1 at page 10 of the present specification supports these limitations. Hybridization conditions have also been amended to the nucleotide sequence of (C) as supported by the present specification at page 43, lines 12-21. Also, the recitation of

"(A) or (B)" in limitation (C) of claim 1 has been replaced with SEQ ID NO:15. Other grammatical changes have been made to claim 1. The recitation of "generation of" in claims 2 and 10 has been replaced with "the formation of." The recitation of "GM1a" in claim 3 has been replaced with the full name of Galb1-3GalNAcb1-4(NeuAca2-3)Galb1-4G1cb1-1'Cer as supported by Table 1, page 10 of the present specification. Claim 3 has also been amended to indicate that incubation in 20 mM Tris-hydrochloric acid (pH 7.5) containing 0.1% polidocanol at 37°C for 24 hours does not decrease activity of the polypeptide, whereas incubation in 20 mM Tris-hydrochloric acid (pH 7.5) containing 0.1% polidocanol at 60°C for 1 hour decreases activity of the polypeptide to about 30%. This limitation is supported by the present specification at page 11, lines 16-21. Claim 6 has been amended to replace "transformant" with "transformed cell" and claims 11-13 have been amended to remove the recitation of "antisense." Claim 20 has been amended to replace the recitation of "antisense" with "complementary" and to remove the recitation of "and/or in a tissue." Accordingly, no new matter has been added.

Applicant further submits that no new issues have been raised by way of the present submission. For instance, the claims have simply been amended to clarify the present invention. The number of issues is reduced, for instance, by the inclusion of hybridization conditions in claim 1 and defining "ceramidase activity" in (C) and (D) of claim 1 as requested by the Examiner. None of the amendments presents issues which would require the burden of additional search and/or consideration on the part of the Examiner. Accordingly, no new issues have been raised.

In the event that the present submission does not place the application into condition for allowance, entry thereof is respectfully requested as placing the application into better form for appeal.

Objection to the Specification

At page 2, paragraph 4 of the outstanding Office Action, the Examiner has maintained the objection to the specification for the

use of abbreviations. Specifically, the Examiner maintains that "GM1a" is an abbreviation and therefore the specification must be amended to recite the entire proper name of this term.

Applicant traverses and submits that the specification has been amended to recite the full name of "Galb1-3GalNAcb1-4(NeuAca2-3)Galb1-4G1cb1-1'Cer" for "GM1a." Accordingly, this objection is moot. Reconsideration and withdrawal thereof are requested.

Objections to the Claims

At page 2, paragraph 6 of the outstanding Office Action the Examiner has maintained the objection that that claims 1, 2, 3, 6, 10, and 14 are generally narrative and indefinite for failing to conform to current U.S. practice, and requests that these claims be rephrased into proper English. Applicant respectfully traverses.

Concerning claim 1, Applicant has replaced the recitation of "any one of the above (A) to (C) via" with "(C) due to." Accordingly, limitation (D) of claim 1 is no longer redundant.

Regarding claims 2, 3, 10, and 14, the Examiner has requested that these claims be rephrased with more correct English. Applicant traverses and submits that these claims recite suitable

language. However, in an effort to further prosecution, Applicant has made certain idiomatic amendments to these claims.

Concerning claim 6, the Examiner asserts that the recitation of "transformant" includes man. Applicant traverses and submits that claim 6 has been amended to recite a "transformed" cell, thus, man is not included.

In summary, Applicant respectfully submits that the objections to the claims have been addressed. Reconsideration and withdrawal of these objections are requested.

Issues under 35 U.S.C. § 112, first paragraph

At page 2, paragraph 7 to page 3, paragraph 2 of the Office Action, the Examiner has rejected claims 1-7, 9-14, and 21 under 35 U.S.C. § 112, first paragraph for allegedly containing subject matter not enabled by the specification. Applicant respectfully traverses.

First, the Examiner asserts that any and all sequences which hybridize to SEQ ID NO: 15 or the nucleotide sequences encoding SEQ ID NO: 14 are not enabled because the hybridization conditions recited in part (C) of claim 1 are "incomplete and low." Applicant

disagrees and submits that claim 1, part (C) has been amended to include more stringent conditions.

In summary, Applicant submits that those of skill in the art are fully able to make and use the invention as currently claimed without undue experimentation. Reconsideration and withdrawal of this rejection are requested.

Definition of "Ceramidase Activity"

Applicant has amended the recitation of "a polypeptide possessing a ceramidase activity" in parts (C) and (D) of claim 1 to recite "a polypeptide having activity of hydrolyzing any one of substances selected from the group consisting of (i) N-Lauroylsphingosine, (ii) N-Palmitoylsphingosine, (iii) N-Stearoylsphingosine, (iv) N-Palmitoylsphinganine, (v) N-Stearoylsphinganine, and (vi) 12-((N-(7-nitrobenz-2-oxa-1,3-diazol-4-yl)amino)dodecanoyl)sphingosine. At the interview conducted on June 17, 2004, the Examiner had suggested replacing the above noted language with "catalyzes hydrolysis of 12-((N-(7-nitrobenz-2-oxa-1,3-diazol-4-yl)amino)dodecanoyl)sphingosine." However, as illustrated in

Table 1, at page 10 of the present specification, the polypeptide of claim 1, parts (C) and (D), has activity of hydrolyzing each of the above (i)-(vi). Accordingly, claim 1, parts (C) and (D) have been amended to reflect this issue.

Issues under 35 U.S.C. § 112, second paragraph

The Examiner has rejected claims 1-14 under 35 U.S.C. § 112, second paragraph for the reasons recited at pages 3-4 of the outstanding Office Action. Applicant respectfully traverses each of these rejections.

Concerning claim 3, the Examiner rejects the use of the abbreviation "GM1a." Applicant traverses and submits that claim 3 has been amended to include the full name of "Galb1-3GalNAcb1-4(NeuAca2-3)Galb1-4G1cb1-1' Cer."

The Examiner has also asserted that "sulfatide" as recited in claim 3, is improper. Applicant traverses and submits that "sulfatide" is one of a class of cerebroside sulfuric esters as shown in the attached 1994 Catalog of SIGMA, page 955 and "Dorland's Illustrated Medical Dictionary", 26th Edition, page 1273 (1981). Accordingly, those of skill in the art understand the metes and bounds of these terms.

The Examiner has also rejected various language in claims 14 and 21 for allegedly being indefinite. Applicant traverses and submits that claims 14 and 21 have been cancelled, thus these rejections are moot.

Issues under 35 U.S.C. § 103(a)

The Examiner has rejected claims 14 and 21 under 35 U.S.C. § 103(a) for allegedly being obvious over Marra et al. (Database: EST, Accession number AA920146) in view of the "state of the art." Applicant respectfully traverses this rejection. Claims 14 and 21 have been cancelled; accordingly, this rejection is moot. Reconsideration and withdrawal thereof are requested.

In view of the above, Applicant respectfully submits that all currently pending claims are in condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw all rejections and allow the currently pending claims.

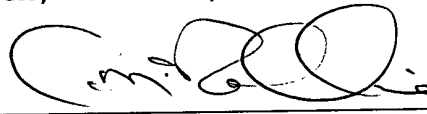
Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact the undersigned at the telephone number below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

Pursuant to the provisions of 37 C.F.R. §§ 1.17 and 1.136(a), the Applicant hereby petitions for an extension of one (1) month to July 23, 2004, in which to file a reply to the Office Action. The required fee of \$110.00 is enclosed herewith.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

Respectfully submitted,

BIRCH, STEWART, KOLASCH & BIRCH, LLP

By 

Marc S. Weiner, #32,181

Craig A. McRobbie, #42,874

MSW/CAM/mmi
1422-0493P

P.O. Box 747
Falls Church, VA 22040-0747
(703) 205-8000

Attachments: (1) 1994 Catalog of SIGMA, page 955; and
(2) Dorland's Illustrated Medical Dictionary, 26th Edition, p.1273, 1981.